

**U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT LANL-ARC-99-05

OF

LOS ALAMOS NATIONAL LABORATORY

AT

LOS ALAMOS, NEW MEXICO

AUGUST 9 - 13, 1999

Prepared by: _____ **Date:** _____

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Approved by: _____ **Date:** _____

**Robert W. Clark
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1.0 EXECUTIVE SUMMARY

This Quality Assurance (QA) Compliance Audit was conducted at the Los Alamos National Laboratory (LANL), Los Alamos, New Mexico on August 9-13, 1999, to evaluate QA program elements directly related to LANL work activities for compliance to the Quality Assurance Requirements Document (QARD) and implementing procedures at the LANL.

The audit team determined that LANL has effectively implemented the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) OCRWM QARD document, (DOE/RW-0333P), Revision 8, and the LANL's implementing procedures.

QA program elements 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 15.0, 16.0, 17.0, Supplements I, II, III, V and Appendix C are effectively implemented. This satisfies OCRWM requirements to perform an annual compliance based audit. Currently elements 3.0, 8.0, 9.0, 10.0, 13.0, 14.0, 18.0, and Supplement IV are not implemented by LANL.

No conditions adverse to quality are identified as a result of the audit. In addition, there are no instances of conditions corrected during the audit as addressed in Section 5.5 of this report. The audit team did not identify any recommendations during the audit as addressed in Section 6.0 of this report.

2.0 SCOPE

Auditors representing the DOE's Office of Quality Assurance (OQA) conducted a compliance audit to evaluate the LANL's implementation of the OCRWM QA Program as described in the QARD and implementing procedures at the LANL facilities.

In addition, the audit team reviewed the status of open and closed OCRWM deficiency documents identified during previous QA audits and surveillances to determine the effectiveness of completed corrective actions by LANL.

The audit team conducted interviews and reviews of documentation to evaluate the adequacy, compliance, and effectiveness of implementation of the OCRWM QA program at LANL.

In accordance with the approved audit plan, the following QA program elements were evaluated:

QA Program Elements

1.0	Organization
2.0	QA Program
4.0	Procurement Document Control
5.0	Implementing Procedures
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
Supp I	Software
Supp II	Sample Control
Supp III	Scientific Investigation
Supp V	Control of the Electronic Management of Data
Appendix C	Mined Geologic Disposal System

The following QA program elements were not reviewed during the audit, since LANL is not currently implementing them:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits
Supp IV	Field Surveying
Appendix A	High-Level Waste form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM

The following list represents members of audit team and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Elements</u>
Michael A. Goyda, Audit Team Leader, OQA	1.0 and Supplements I, III & V
Donald J. Harris, Auditor, OQA	2.0 and Supplement III
Victor J. Barish, Auditor, OQA	2.0, 4.0, 5.0, 6.0, 7.0 & Appendix C
Charles T. Taylor, Auditor, OQA	12.0, 15.0, 16.0, 17.0 & Supp. II

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at LANL on Monday, August 9, 1999. Daily debriefings were held to apprise LANL management and staff of the progress of the audit and any identified conditions adverse to quality. A post-audit meeting was conducted at LANL on Friday, August 13, 1999.

Attachment 1, Personnel Contacted During the Audit, includes those personnel that attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF RESULTS

5.1 Program Effectiveness

The audit team concluded that for the QA Program elements examined through the audit LANL has effectively implemented the QA program for the scope of this audit.

The results for each QA Program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

5.2 Stop Work or Immediate Corrective Action Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of the audit.

5.3 QA Program Implementation

A Summary Table of Audit Results is provided in Attachment 2. Details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.3.1. Audit Process

Thirteen members of the LANL staff working on the Yucca Mountain Site Characterization Project (YMP) were interviewed during the audit. In each case, the personnel interviewed were knowledgeable and demonstrated competence for the work activities for which they were responsible. In addition, interviews and a document review determined that the LANL organizational structure, as represented by LANL-YMP-QP-01.4, Rev. 5, "The Los Alamos YMP Organization and Quality Program Description," were in place as depicted.

LANL personnel interviews and review of training records were used to evaluate the implementation of QARD and LANL procedures to address personnel qualification and training. Project Administrative Procedures

AP-2.1Q and AP-2.2Q have recently superseded corresponding LANL procedures. As such, the audit team concentrated the audit activity on the LANL procedures that were in effect for the audit period. The audit team concluded that LANL met the requirements of the QARD to effectively implement QA program requirements. The audit team also verified through personnel interviews and review of records that personnel classified as “staff augmentation” are being indoctrinated and trained to the YMP QA Program. In addition, LANL personnel interviews, review of the Requirements Traceability Matrix Database, and review of records were conducted by the Audit Team to verify implementation of LANL’s QA Program. The audit team concluded that LANL’s QA Program and implementation were adequate and effective as demonstrated throughout the conduct of the audit and documented in the audit checklist

LANL’s activities related to the implementation of the QARD, Section 4, regarding procurement document control has been limited as the transition of the procurement function to the Civilian Radioactive Waste Management System Management & Operating Contractor (CRWMS M&O) has been implemented. As a function of the extent of condition evaluation performed under Corrective Action Request (CAR) VAMO-98-C-005, procurement documents were evaluated and results documented. Therefore, the audit team evaluated LANL’s compliance with the existing process of forwarding all procurement requests for quality affecting procurements to the CRWMS M&O. The audit team determined through interviews with appropriate LANL personnel and review of procurement requests that the LANL on-site QA representative has screened all LANL procurement requests and that quality affecting procurement requests are being forwarded to the CRWMS M&O for processing.

Based on interviews with LANL personnel and review of records and databases, the audit team determined that LANL’s QA Program has established adequate control of implementing documents and has effectively implemented these program measures.

Relative to document control, the audit team conducted interviews with appropriate LANL personnel and review of LANL’s procedure database and records to determine that the electronic version of procedures match the approved effective revision. The audit team concluded that controls are established to assure the adequacy and accuracy of the database and that records submitted to the Records Processing Center in Las Vegas are complete through the submittal. LANL has established a controlled procedure database that does not require distribution of controlled copies.

The audit team conducted interviews and documentation reviews to

evaluate the implementation of QARD, Section 7, regarding the control of purchased items and services. As previously noted, the CRWMS M&O has assumed the function of procuring quality affecting items and services. Therefore, the audit team concentrated on those aspects of QARD, Section 7, that are implemented by LANL. Through interviews with LANL personnel and review of records and copies of Supplier Evaluation Reports addressed by AP-7.4Q, "Maintenance Of The Office Of Civilian Radioactive Management Qualified Suppliers List," the audit team concluded that LANL has effectively implemented the applicable requirements. In addition, the audit team also reviewed procurement records for acceptance of an analytical service controlled under LANL procurement procedure LANL-YMP-PQ-04.6 and determined that the process was effectively implemented in addressing QARD, Appendix C requirements.

Interviews, documentation reviews and physical observations of equipment were conducted to evaluate the process controls for Measuring and Test Equipment (M&TE). A new Yucca Mountain Administrative Procedure, YAP-12.3Q, for control of M&TE, became effective on July 30, 1999, and superceded LANL-YMP-QP-12.3. Since LANL-YMP-QP-12.3 was in effect since the 1998 audit, this procedure was used to evaluate the M&TE program implementation. LANL is in the process of transitioning to the YAP-12.3Q. Documentation reviews consisting of M&TE certificates, Evaluation Reports, and Scientific Notebook (SN) entries revealed that the program met the QARD and procedure requirements.

As determined through the review of LANL's corrective action program, LANL only generates Deficiency Reports (DR's) in accordance with AP-16.1Q, since LANL does not perform activities related to products or items. One DR had been initiated by LANL since the 1998 audit that identified procurement of M&TE services from a source not on the Qualified Suppliers List. This DR was evaluated for Remedial and Corrective Actions and is addressed in Section 5.5.5 of this report.

A total of eight (8) DR's were closed since the 1998 audit and two that remain open were added to the respective sections of the audit checklist for determining the status of corrective actions. The statuses of these DR's are addressed in Section 5.5.5 of this report.

Interviews and documentation reviews were conducted to evaluate the effectiveness of implementation of the QA Records. The reviews performed in this area throughout the conduct of the audit revealed that LANL has met the QARD and procedure requirements as documented throughout the audit checklist.

LANL's corrective actions relative to CRWMS M&O CAR LVMO-98-C-006 regarding software qualification was reviewed during the audit. As revealed during the audit, LANL is currently addressing the software qualification of twenty one (21) programs as a portion of corrective actions addressing this CAR. LANL personnel revealed that they were nearing completion of qualification of each software program to the requirements of AP-SI.1Q, Revision 0, "Software Configuration Management" and LANL-YMP-QP-3.21, Revision 7, "Software Life Cycle." As revealed during the audit, LANL personnel have been directed to address the software qualification requirements of revision 1 of AP-SI-1.Q. LANL Management with the CRWMS M&O was addressing this matter. As corrective actions for this CAR are in process and not completed, this area was not audited.

Samples from Busted Butte and Nye County activities were selected for review and proper implementation of the QARD and procedure requirements. Interviews with the Principle Investigator (PI), reviews of SNs, and physical traceability of samples reflects adequate implementation of the requirements associated with collection, Sample Management Facility processing, PI SN entries, proper labeling, and traceability of samples.

Efforts to control SNs were examined during the audit. Three (3) SNs were sampled and reviewed during the audit and determined to be in compliance with LANL-YMP-QP-03.5, Revision 8, "Documenting Scientific Investigations." Further, LANL has undertaken efforts to transition control of SNs to the requirements of AP-SIII.1Q, "Scientific Notebooks." This transition was in process with no deficient conditions identified and scheduled to be completed within the allotted transition period.

LANL's efforts to plan and control work activities were examined during the audit. As presented during the audit, LANL has developed a "AMR/PMR Status Tracking Spreadsheet," that reflects the management of eleven (11) in process Analysis Model Reports (AMR). The AMRs represent LANL's planning efforts to address the requirements of AP-2.13Q, "Technical Product Development Planning and LANL-YMP-QP-02.14, "Preparation, Review and Approval of Work Plans. The LANL planning efforts reviewed serve as a portion of the response to DR LVMO-98-D-027.

Particular effort was devoted to the review of two (2) available draft LANL Work Plans for the development of AMR's, "The Unsaturated Zone Transport Field Test at Busted Butte," and "Natural Analogue Studies: Flow and Transport in Ash Flow Tuff at Pena Blanca – Analogue to Radionuclide Retention." As these documents were in the draft stage, the audit team provided cursory review and comment; however, the audit team concluded that "The Unsaturated Zone Transport Field Test at Busted Butte" Work Plan, as reviewed during the audit, represents a premium example of a necessary lower level work planning document to identify project participants and control work prior to initiating project work activities.

LANL's corrective actions relative to CRWMS M&O DR LVMO-98-D-055 regarding the control of the electronic management of data was reviewed during the audit. This CRWMS M&O DR documented that the CRWMS M&O (to include labs, LANL, Lawrence Livermore National Laboratory, etc.) failed to have a process in place to determine what databases utilized as a controlled source of information were required to be controlled under QARD, Supplement V. Corrective actions for this DR are in process across the entire CRWMS M&O with an extension date granted by OQA until 9/1/99. As corrective actions for this DR are in process and not completed, this area was not audited.

5.3.2 Audit Results

The audit team determined that LANL has effectively implemented the OCRWM QA Program in accordance with the DOE OCRWM QARD document, (DOE/RW-0333P), Revision 8, and the LANL's implementing procedures. As a result, no new conditions adverse to quality are identified.

5.4 Summary of Conditions Adverse to Quality

The audit team identified no new conditions adverse to quality.

5.4.1 Corrective Action Requests (CAR)

None

5.4.2 Deficiency Reports (DRs)

None

5.4.3 Performance Reports (PRs)

None

5.4.4 Deficiencies Corrected During the Audit (CDA)

None

5.4.5 Follow-up of Previously Issued Deficiency Documents

Follow-up of DR LANL-98-D-115 was performed during the audit. The DR identified an isolated instance where a PI for EH/PH studies was not trained to LANL specific procedures. Subsequent investigation revealed that the PI was trained, however documentation of the training had not been submitted. This condition was satisfactorily resolved, verified and closed by the OQA on 10/14/98. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-99-D-074 was performed during the audit. The DR identified that LANL failed to identify a particular procurement as a "Q" activity. Actions to preclude recurrence (OQA Survey to be conducted 8/31/99) are in process. This DR will remain open pending completion of corrective actions. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-98-D-114 was performed during the audit. This DR documented that LANL had not provided a copy of a controlled document at the YMP Exploratory Studies Facility location. This DR was satisfactorily resolved, verified and closed by OQA on 10/16/98. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-98-D-113 was performed during the audit. This

DR documented that the LANL had failed to identify a particular calibration instrument with a "calibration before use" label. This condition was corrected at the YMP site. This DR was satisfactorily resolved, verified and closed by the OQA on 11/12/98. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-98-D-119 was performed during the audit. This DR documented that LANL failed to document the use of specific piece of M&TE in a specific SN, failed to identify a particular calibration instrument with a "calibration before use" label and a particular M&TE Report had been completed after the instrument had been put into service. These conditions were treated as isolated incidents and were resolved, verified and closed by OQA on 11/16/98. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-98-D-110 was performed during the audit. This DR documented that the LANL had failed to identify the proper QA indexing information on the first page of noted records packages. This DR was satisfactorily resolved, verified and closed by the OQA on 10/14/98. No new instances of this condition were identified during the audit.

Follow-up of DR LANL-99-D-006 was performed during the audit. This DR documented that LANL software DIFCEL was not qualified to meet QARD requirements 1.2.3, 1.2.4 & 1.2.5. Subsequent evaluation of this software identified it as a Non Qualified as documented in a SN containing appropriate justification. This DR was resolved, satisfactorily verified and closed by the OQA on 2/17/99. Actions to preclude recurrence of this condition are referred to corrective actions under the resolution of CAR LVMO-98-C-006.

Follow-up of DR LANL-98-D-108 was performed during the audit. This DR documented that the LANL had failed to provide traceability between LANL technical reports, applicable SNs and Data Tracking Numbers. This DR was closed by the OQA on 5/28/99. Actions to correct this condition including actions to preclude recurrence are referred to corrective actions under the resolution of CARs LVMO-98-C-002 and LVMO-99-C-001.

Follow-up of DR LANL-98-D-120 was performed during the audit. This DR documented that the LANL had failed to perform a technical review of a specific SN. This DR was satisfactorily resolved, verified and closed by the OQA on 1/13/99. In addition, the CRWMS M&O has undertaken a review of all LANL SNs. This action remains in process with the results on the Technical Assurance Reviews being documented within each SN. No new instances of conditions adverse to quality with regard to SNs were identified during the audit.

Follow-up of DR LANL-99-D-007 was performed during the audit. This DR documented that the LANL had failed to properly identify C Well Core samples used in laboratory testing as unqualified core. This DR remains open and a disposition to resolve the issue is pending within the CRWMS M&O with a determination to be completed by 9/6/99.

6.0 RECOMMENDATIONS

The audit team identified no recommendations as a result of the audit.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Summary Table of Audit Results

ATTACHMENT 1

Personnel Contacted During the Audit

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Meeting</u>	<u>Contacted During Audit</u>	<u>Post-Audit Meeting</u>
Burningham, Andrew	LANL QA Liaison		X	
Bish, Dave	LANL Principal Investigator		X	
Chipera, Steve	LANL Cal. Lab Technician		X	
Conca, James	LANL Rad. Geochem. Section Lead	X		
Dixon, Paul	LANL Lab Lead	X	X	X
Friend, John	LANL OQA Site Representative	X	X	X
Gray, Elizabeth	LANL Records & Document Control Coordinator	X	X	X
Harrington, Charles	LANL Project Lead Performance Confirmation		X	
Hayes, Larry	CRWMS M&O NEPO Ops Mgr.			X
Martinez, Cleoves	LANL TA Lead	X	X	X
Stone, Dan	LANL Tech Data Specialist	X		X
Whitlock, Valerie	LANL Software Mgt. Coord.	X	X	X
Wilcox, John	LANL QA Specialist	X		X
Wolfsberg, Laura	LANL Principal Investigator		X	
Young, James	LANL Tech. Assurance/ Data Coordinator	X	X	X

ATTACHMENT 2

SUMMARY TABLE OF AUDIT RESULTS

QA Program Element	QA Program Document	Details (Checklist)	CDA	Recommendation	Program Effectiveness	Program Compliance
Organization	QP-01.4, R 5 QP-01.3, R 5	Pgs. 1 thru 3			SAT	SAT
QA Program & Planning	QP-02.12, R 3 QP-02.15, R 4 QARD, 2.2.9, R 8 QP-02.5, R 4 QP-02.7, R 4 QARD, 2.2.12, R8 QP-02.14, R 0 AP-2.13Q, R 0 AP-2.1Q, R 0 AP-2.2Q, R 0	Pgs. 4 thru 25			SAT	SAT
Procurement Document Control	QP-04.6, R 6	Pgs. 26 thru 28			SAT	SAT
Implementing Documents	QP-06.2, R8 AP-5.2Q	Pgs. 29 thru 32			SAT	SAT
Document Control	QP-06.1 R 8	Pgs. 33 thru 35			SAT	SAT
Control of Purchased Items & Services & Appendix C	AP-7.4Q, R3 QP-04.6, R 6	Pgs. 36 thru 38			SAT	SAT
Control of M & TE	QP-12.3, R 4	Pgs. 39 thru 42			SAT	SAT
Control of Nonconformances	YAP-15.1Q, R4	Pgs. 43 thru 49			SAT	SAT
Corrective Actions	AP-16.1Q, R 4	Pgs. 50 thru 52			SAT	SAT
QA Records	AP 17.1Q, R 1	Pgs. 53 thru 59			SAT	SAT
Supplement I, Software	AP-SI.1Q, R 1	Pgs. 60 thru 75			N/A	N/A
Supplement II, Control of	QP-08.1, R 6	Pgs. 76 thru 83A			SAT	SAT

QA Program Element	QA Program Document	Details (Checklist)	CDA	Recommendation	Program Effectiveness	Program Compliance
Samples						
Supplement III, Scientific Investigation	AP-SIII.1Q, R 0 AP-SIII-3Q, R 0 AP-3.12Q, R 0 AP-3.10Q, R 0 AP-3.14Q, R 0 AP-3.15Q, R 0 QP-03.5, R 8 QP-03.25, R 3 QP-08.3 R 6 AP-3.11Q, R 0 QP-3.28, R 0	Pgs. 84 thru 122			SAT	SAT
Supplement V, Control of Electronic Mgt. Of Data	QARD, Sup. V, R 8	Pgs. 123 & 124			N/A	N/A

LEGEND:

UNSAT	Unsatisfactory
SAT	Satisfactory
N/A	Not Audited
CDA	Corrected During Audit